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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,709	03/05/2002	Robert G. Gallaher	RNBO-1-1003	7467

7590 06/13/2003

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,709	GALLAHER, ROBERT G.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group III, claims 14-20, in Paper No: 4 is acknowledged. The traversal is on the ground(s) that the method claims of group III links the method claims of group II, and the method claims of group II are sufficiently linked to the method claims of group I, because all method claims utilize compounds that treat viral infections by targeting microtubule related processes. This is not found persuasive because Paper No: 3, page 3 points out one would not have to practice the various methods at the same time to practice just one method alone. Applicant put forth no argument for the traverse against the species election of taxanes, therefore, it will be treated as an election without traverse.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 8/6/02 (Paper No: 2) is acknowledged. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites "... the method comprising: **receiving** an effective amount..." . This is indefinite for lacking at least one active method step. Examiner suggests replacing "receiving" with either "contacting" or "administering".

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The terms Herpesvirus-1 (HSV-1), Herpervirus-2 (HSV-2), Herpes Simplex 6 (HSV-6), Herpes Simplex 7 (HSV-7), Herpes Simplex 8 (HSV-8), and Human Infectivity Virus (HIV) in claim 19 are used by the claim to mean Herpesvirus-1 (HSV-1), Herpervirus-2 (HSV-2), Herpes Simplex 6 (HSV-6), Herpes Simplex 7 (HSV-7), Herpes Simplex 8 (HSV-8), and Human Infectivity Virus (HIV), while the accepted meaning is Herpes simplex virus type 1, Herpes simplex virus type 2, Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), Human herpesvirus 8 (HHV-8), and Human Immunodeficiency Virus (HIV), according to Fields "Virology" 3rd edition, page 26, table 4.

The terms are indefinite because the specification does not clearly redefine the terms.

Claims 15-18 and 20 are included in this rejection for depending upon a rejected claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the topical treatment of Herpes simplex virus type 1 cold sores and Herpes simplex virus type 2 genital lesions via application of taxanes to the skin, does not reasonably provide enablement for the topical treatment of Cytomegalovirus (CMV), Varacella-Zoster Virus (VZV), Epstein Barr virus (EBV), Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), Human herpesvirus 8 (HHV-8), Human Papilloma Virus (HPV), Vaccinia Virus (VV), Adenovirus, Parvovirus, Human Immunodeficiency Virus (HIV), or rabies virus via administration of any compounds which target the microtubule process in cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of

experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The invention is drawn to a method to treat viral infection in mammals, the method comprising: receiving an effective amount of a compostion, taxanes, targeting the microtubule process in mammalian cells, the effective amount being delivered by a topical route of administration to reduce viral infections in dermal lesions and inflamed areas. The viruses targeted are: Herpes simplex virus type 1, Herpes simplex virus type 2, Cytomegalovirus (CMV), Varacella-Zoster Virus (VZV), Epstein Barr virus (EBV), Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), Human herpesvirus 8 (HHV-8), Human Papilloma Virus (HPV), Vaccinia Virus (VV), Adenovirus, Parvovirus, Human Immunodeficiency Virus (HIV), and rabies virus

The state of the prior art and the predictability or lack thereof in the art:

Based on the teachings of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991). Bernstein (Antiviral Chemotherapy: General Overview, Wright State School of Medicine, Division of Infectious Diseases, 2000) discloses the unpredictability of antivirals for Treatment. Bernstein teaches Acyclovir has been available for the last decade. It was originally released as a topical ointment. Acyclovir was most active against Herpes simplex virus, had some activity against varicella-zoster virus, little activity against Epstein-barr virus and virtually no activity against CMV, see page 1. Disease manifestations of CMV and Epstein-barr virus are usually not on the skin for topical treatment.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The lack of working examples, limited to treating HSV skin lesions using a single extract, for *in vitro* use in the instant specification provide no enablement for *in vitro* use in the treatment of Cytomegalovirus (CMV), Varacella-Zoster Virus (VZV),and Epstein Barr virus (EBV). The absence of evidence and working examples provides no enablement for *in vivo* or *in vitro* use in the treatment of Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), Human herpesvirus 8 (HHV-8), Human Papilloma Virus (HPV), Vaccinia Virus (VV), Adenovirus, Parvovirus, Human

Immunodeficiency Virus (HIV), and rabies virus

The breadth of the claims and the quantity of experimentation needed: The breadth of the claims, coupled with the quantity of experimentation needed to enable the treatment of Cytomegalovirus (CMV), Varacella-Zoster Virus (VZV), Epstein Barr virus (EBV), Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), Human herpesvirus 8 (HHV-8), Human Papilloma Virus (HPV), Vaccinia Virus (VV), Adenovirus, Parvovirus, Human Immunodeficiency Virus (HIV), and rabies virus *in vitro* is deemed excessive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,406,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application, claim 14, is drawn to a method of treating viral infections in mammals, the

method comprising: receiving an effective amount of a compostion, taxanes, the effective amount being delivered by a topical route of administration to reduce viral infections in dermal lesions and inflamed areas. Claim 1 of the '722 patent describes a topical method of treating lesions caused by Herpes Simplex Virus 1 (HSV-1), whereby the composition comprises effective amounts of taxane, olive oil and beeswax. Claim 15 of the instant application is drawn to a composition, taxanes. Claims 1, 3, 5, and 7 of the '722 patent describe the use of taxane in the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claim 16 of the instant application describe compositions further including solubilizers, lubricants, emulsifiers, waxes, solutions, preservatives, humectants, and analgesics. Claims 1, 3, 5, and 7 of the '722 patent describe the use of beeswax in the composition. Claim 17 of the instant application describes various solutions for use in the composition. Claims 1, 3, 5, and 7 of the '722 patent describe a composition of taxane, olive oil and beeswax. Claim 18 of the instant application describes various solubilizers for use in the composition. Claims 1, 3, 5, and 7 of the '722 patent describe a compostion containing olive oil. Claim 19 of the instant application describes viruses treated with the composition, which include Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2). Claims 1, 3, 5, and 7 of the '722 patent describe the treatment of Herpes Simplex Virus 1 (HSV-1) and Herpes Simplex Virus 2 (HSV-2) with the composition. Claim 20 of the instant application describes a topical route of administration. Claims 2, 4, 6, and 8 of the '722 patent describe a topical route of administration. Thus the claims are considered to be obvious variations (by claim terminology) of the same composition, and not patentably distinct. Absent evidence to the contrary, the composition of the '722 patent is assumed to have the same targeting effect on the microtubule process of mammalian cells as the

instant application composition.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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1654
6/5/03
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